K113508

AUG 3 1 2012

510(k) SUMMARY

510(k) Owner	Armadillo Medical, LLC 5363 Balboa Blvd. Suite 246 Encino, CA 91316 TEL: 855.255.3310 FAX: 818.783.9059
Contact person	Robyn Scopis Regulatory Consultant to Armadillo Biomedical Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 TEL: 949.422.3853 FAX: 949.552.2821 EMAIL: robyn@regulatoryspecialists.com
Date summary was prepared	August 20, 2012
Name of device	DacryoCath
Common Name	Lacrimal duct balloon catheter
Classification Name	Lacrimal Stents and Intubation Sets
Regulation	Pre-Amendment
Product Code	OKS
Predicate	K935233

Description

The lacrimal duct catheter is a sterile, single use, non-pyrogenic disposable balloon catheter consisting of a semi-flexible stainless steel hypotube core and polyethylene terephthalate balloon tubing. The balloon is designed to inflate to a known diameter and length at the specific pressure. Markings are present 10 and 15 mm proximal to the beginning of the working portion of the balloon, which helps indicate when the balloon is placed correctly in the lacrimal system. The overall length of the catheter is 6 inches (15.24 cm) long. There is an opening on the distal end of the catheter hypotube to accommodate irrigation solutions. The Y-hub on the proximal end of the catheter has a luer port for inflation of the balloon catheter (labeled "inflation" with a red band) and a second luer port for irrigation through the balloon catheter (labeled "irrigation"). The balloon catheter is available in a 2 mm and 3 mm inflated diameter. The 3 mm balloon has a length of 15 mm and a deflated profile of approximately 1.1 mm. The 2 mm balloon has a length of 15 mm and a deflated profile of approximately 1.0 mm.

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Description continued:

The balloon has a 5 mm inflated diameter and a length of 10 mm. The deflated profile of the 5 mm balloon is approximately 1.2 mm.

Intended Use

The lacrimal duct catheter is intended for use during dilation of the obstructed nasolacrimal duct.

Indications for Use

The lacrimal duct catheter is indicated for use during dilation of the obstructed nasolacrimal duct in the following populations:

a. The 2mm catheter is indicated for use during dilation of the obstructed nasolacrimal duct obstruction in patients over 12 months of age and under 30 months of age.

b. The 3 mm catheter is indicated for use during dilation of the obstructed nasolacrimal duct in children over 30 months of age.

c. The 5mm catheter is indicated for use in adults during dilation of a lacrimal duct obstruction or blocked dacryocystorhinostomy ostium as a result of the following: functional or complete nasolacrimal duct obstruction, dacryocystitis, or failed dacryocystorhinostomy.

Technological Characteristics

The predicate and the DacryoCath were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Material Characteristics

Both the Predicate and DacryoCath are made of Stainless Steel and Polyethylene.

Design Characteristics

Both the Predicate and DacryoCath are designed to be used as lacrimal duct balloon catheters.

Operating Characteristics

Both the Predicate and DacryoCath are operated by placing the catheter into the canaliculus, inflate the balloon to 8atm with 10cc sterile saline, and inflate for 90seconds to dilate the obstructed nasolacrimal duct.

Intended Use

Both the Predicate and DacryoCath have the same intended use: The lacrimal duct catheter is intended for use during dilation of the obstructed nasolacrimal duct

Technological Characteristics

Similar technological characteristics continued:

Balloon Length –3 mm

Predicate – 15mm

DacryoCath – 15mm

Balloon Length – 5mm

Predicate – 10mm

DacryoCath – 10mm

The predicate and the DacryoCath were compared in the following areas and found to have minor different technological characteristics. The following differences have been determined, through non-clinical performance testing, to not have any impact on the safety or efficacy of the DacryoCath when used as indicated:

Length of Catheter

Predicate – 24cm

DacryoCath – 15.24cm

Balloon Length (2mm Balloon only)

Predicate – 13mm

DacryoCath – 15mm

Irrigation Port –

Predicate – None Available

DacryoCath - Yes

The following non-clinical performance tests were conducted:

Biocompatibility to ISO10993

Cytotoxicity	PASS
Sensitization	PASS
Irritation	PASS

ISO Guinea Pig Maximization Sensitization Test

The test article did not elicit a sensitization response under the conditions of this assay.

ISO Intracutaneous Reactivity Test

The requirements of ISO Intracutaneous Reactivity have been met by the test article.

Rabbit Pyrogen Test (Material Mediated) – ISO

The USP 0.9% Sodium Chloride for Injection (NaCl) extract of the test article, Lot #23054 – lacrimal balloon catheters, was evaluated for its potential to produce a pyrogenic response when tested in New Zealand White rabbits. Based on the criteria of the protocol, the test article is considered non-pyrogenic and meets the requirements of the Pyrogen Test, ISO10993-11 guidelines.

Non-clinical performance tests continued:

ISO Acute Systemic Injection Test

The requirements of the ISO Acute Systemic Injection Test have been met by the test article.

MEM Elution GLP Report

The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

Inflation/Deflation Time — PASS

Inflation/Deflation Time testing was conducted to show that the inflation and deflation of the balloons using conventional techniques can be accomplished within a specified time.

Fatigue Testing — PASS

Fatigue testing was conducted to determine the repeatability of balloon inflation without failure using the recommended inflation pressure.

Rupture Testing — PASS

Rupture testing was done on balloons of each diameter and length. Test results show that the balloons will not burst at or below the maximum recommended burst pressure.

Tensile Testing — PASS

Tensile testing was done to test the bond strength at locations where joining methods are used for bonding components of the catheter. Testing demonstrated that all bonds can withstand tensile forces greater than those that may be experienced during clinical use.

ISO 594-1 Testing — PASS

ISO 594-1 testing was conducted for the 6% (Luer) taper for syringes. Under this guidance, the following tests were conducted:

- Gauging
- Liquid Leakage
- Air Leakage
- Separation Force
- Stress Cracking

Packaging Validation		PASS
Transportation	ASTM D169	PASS
Seal Peel Test		PASS
Dye Migration Test	ASTM F1929	PASS
Aerosol Challenge Test		PASS
Accelerated Aging Test		PASS

3.3 weeks @ 55± 4°C
Simulating 0.5 year shelf life

Non-clinical performance tests continued:

EO Sterilization Validation PASS

A microbiological challenge utilizing the half-cycle (overkill) method, using a biological indicator challenge following ISO11135.

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the DacryoCath is substantially equivalent to the predicate as a lacrimal duct balloon catheter.

Clinical performance data

A review of the published peer-reviewed literature was conducted to review appropriate uses, adverse events, and clinical experience with this device type.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 31 2012

Armadillo Biomedical, LLC
c/o Ms. Robyn Scopis
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K113508
Trade/Device Name: DacryoCath
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: OKS
Dated: August 20, 2012
Received: August 29, 2012

Dear Ms. Scopis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113508

Device Name: DacryoCath by Armadillo Biomedical, LLC

Indications for Use:

The lacrimal duct catheter is indicated for use during dilation of the obstructed nasolacrimal duct in the following populations:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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